K122876

OCT 31 2012

Section 7 - 510(k) Summary

Submission By: **Starkey Laboratories**
6600-6700 Washington Avenue So.
Eden Prairie, MN. 55344
Phone: 952-941-6401
Fax: 952-828-9121

Contact: **Ken Meyer**
Regulatory Manager
Starkey World Headquarters
6600-6700 Washington Avenue So.
Eden Prairie, MN. 55344
Phone: 952-947-4734
Fax: 952-828-9121

Date Prepared: **July 20, 2012**

Device Name: **Multiflex Tinnitus Technology™**

Device Trade/ Proprietary Name: Multiflex Tinnitus Technology™

Device Common Name: Tinnitus Masker

Device Class: **Class II**

Classification Name: **21 CFR 874.3400 *Tinnitus Masker***

Classification Panel: **Ophthalmic and Ear, Nose, and Throat Division**

Product Code: **KLW**

Predicate Device: **K110932, GN Resound Tinnitus Sound Generator Module**

Device Description

The Starkey Multiflex Tinnitus Technology™ provides the hearing care professional with an option to treat those patients suffering from tinnitus. It is a firmware functionality option embedded in the signal processing stage of a digital hearing aid. The Multiflex

Tinnitus Technology™ firmware generates broadband white noise that periodically fluctuates in amplitude and frequency to provide relief for those suffering from tinnitus.

The Multiflex Tinnitus Technology™ functionalities and parameters are enabled and adjusted by a hearing care professional to meet the individual needs of the patient.

Intended Use

The Multiflex Tinnitus Technology™ is a tool to generate sounds to be used in a Tinnitus Management Program to relieve patients suffering from tinnitus. The target population is primarily the adult population over 18 years of age.

The Multiflex Tinnitus Technology™ is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional hearing disorders.

The fitting of the Multiflex Tinnitus Technology™ must be done by a hearing professional participating in a tinnitus management program.

Technological Characteristics Comparison

The Starkey Multiflex Tinnitus Technology uses the same basic technology used by the predicate device. It shares the following similarities to the predicate devices:

- The Starkey Multiflex Tinnitus Technology has a similar platform, similar functionality, similar color of sound, similar number of programs, similar circuit type, similar overall stimulus level, similar maximum output characteristics, similar volume/level control approach, and a similar power source as the predicate device.

The technological characteristics of the Starkey Multiflex Tinnitus Technology that differ from the predicate device are:

- Schedule of use
- Amplitude/frequency fluctuation

The schedule of use is supported by an FDA consensus standard with amplitude/frequency fluctuation being supported by a number of research studies included in this submission.

The methodology of such implementation in the Multiflex Tinnitus Technology™ introduces no new energies, frequencies or levels of such that may introduce risk or effectiveness concerns.

Performance Data

Starkey Laboratories has conducted a risk analysis and performed the necessary verification and validation activities to demonstrate that the design outputs meet the design inputs. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Conclusions

Based on the similar indications for use, technical characteristics and results from performance testing, Starkey Laboratories considers the Starkey Multiflex Tinnitus Technology substantially equivalent to the GN ReSound Tinnitus Sound Generator under K110932.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

OCT 31 2012

Starkley Laboratories
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K122876
Trade/Device Name: Multiflex Tinnitus Technology™
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: September 18, 2012
Received: September 19, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122876

Section 5. Indications for Use

510(k) Number: Reference Document K12xxxx

Device Name: Multiflex Tinnitus Technology™

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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Prescription Use X
(Per 21 CFR 801.109)